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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,618	01/11/2002	Fumihiko Kanai	00005.001197	8327

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EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,618	Applicant(s) Kanai et al.
	Examiner Bruck Kifle, Ph.D.	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 11, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim Rejections - 35 USC § 112

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The phrase "An antitumor agent comprising a staurosporin derivative or a pharmaceutically acceptable salt thereof, as an active ingredient, which is represented by the general formula (I)" is unclear as to whether a compound or a pharmaceutical composition is intended. It is also unclear what else is present. The terms "general" and "derivative" are open-ended. If a compound is intended, the phrase "A compound of formula I" along with the structural formula and the definitions of the variables fully defines the compound.

ii) The term "substituted" without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not.

iii) The term "heterocyclic" is indefinite because it is not known how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended.

iv) The term "cycloalkyl"is indefinite because it is not known how many atoms make up the ring and what kind of a ring is intended (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.).

v) It is unclear what is embraced by "a residue of an amino acid".

vi) Claims 2 and 3 are independent claims and should include all of their limitations within themselves.

vii) It is unclear which antitumor agent is intended in claims 18 and 24.

viii) In claims 19 and 25 it is unclear what is accomplished and who needs to have this done. These claims would read on abrogating accumulation action at the G2 or S stage of the cell cycle *in vitro*, abrogating accumulation action at the G2 or S stage of the cell cycle in mammals with below normal action at the G2 or S stage of the cell cycle, abrogating accumulation action at the G2 or S stage of the cell cycle in mammals with normal accumulation action at the G2 or S stage of the cell cycle, or in asymptomatic mammals with up-regulated accumulation action at the G2 or S stage of the cell cycle. The specification fails to teach any benefit to be gained from such actions. Is extensive experimentation required on the part of a potential infringer to determine if his use of Applicants' compounds falls within the limitations of applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967). As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show

that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Claims 20-22 and 26-28 provide for the use of a compound, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-22 and 26-28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 17 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 17 and 23 are drawn to a method of treating a malignant tumor. The specification does not provide enablement for the treatment of a malignant tumor generally. No compound has ever been found that can treat malignant tumors generally even though massive efforts have been directed towards this end. Since this assertion is contrary to what is known in oncology, proof must be provided that this revolutionary assertion has merits. Nearly all

antitumor drugs are effective against only a limited group of related tumors. Therefore, a compound effective against tumors generally would be a revolutionary exception. Applicant is asserting that he succeeded where others have failed. Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaeck 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

In re Buting 163 USPQ 689 establishes that even clinical tests showing that a compound found to be useful in the treatment of two types of cancers was not sufficient for a much broader range.

Claims 9-11 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). All of these claims are drawn to the compound according to claim 1.

Similarly, claims 12-15 are duplicates of any one of claim 2 to 5.

Copious amount of art is found. Therefore, prior art considerations have been limited to the independent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Schupp et al. (Journal of Natural Products (1999), 62(7), 959-962). The claims read on the compounds of RN 239785-04-7P and 239785-05-8P (see CAS abstract and structures attached).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (Journal of Antibiotics (1996), 49(10), 1070-1072). The claims read on compounds of RN 135384-18-8; 135384-19-9; 135384-20-2; 135384-21-3; 135384-98-5; 184180-07-2; 184180-08-3; 184180-09-4; 184180-10-7 and 184180-11-8 (see CAS abstract and structures attached).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Murakata et al. (US 5,604,219). The claims read on compounds in Table 1, cols 13-16 of the reference.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamaoki et al. (US 5,674,867). The claims read on compounds No. I-30-I-33; I47-I-48, etc. (see table 1 of the reference).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (JP 5140168). The claims read on compounds of RN 135384-27-9; 135384-29-1; 149166-82-5 and 149166-84-7 (see CAS abstract and structures).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsubotani et al. (Tetrahedron (1991), 47(22), 3565-74. The claims read on the compound of RN 124843-68-1 (see CAS abstract and structures).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (JP 01149791). The claims read on compounds of RN 124986-48-7 and 124843-68-1 (see CAS abstract and structures).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantrell et al. (Natural Product Letters (1999), 14(1), 39-46) or Funato et al. (Tetrahedron Letters (1994), 35(8), 1251-4). These references each teach compounds of RN 143682-18-2 and 272766-45-7 (Cantrell) and RN 143682-17-1 (Funato) (see CAS abstract and structure). The claims differ by requiring the substituent on the benzene rings at an adjacent position. That is, the claims differ by

being ring position isomers of the prior art compounds. (See also Kinnet et al. (Journal of Organic Chemistry (1992), 57(23), 6327-9) which teaches the compound of RN 143682-18-2.).

Position isomers are well established as being prima facie structurally obvious. See: Ex parte Engelhardt, 208 USPQ 343, 349; In re Mehta, 146 USPQ 284; In re Surrey, 138 USPQ 67; Ex parte Ullyot 103 USPQ 185; Ex parte Naito 168 USPQ 437, 439; In re Norris 84 USPQ 459; Ex parte Allais 152 USPQ 66; Ex parte Henkel 130 USPQ 474; Ex parte Biel 124 USPQ 109; In re Crownse 150 USPQ 554; In re Fouche 169 USPQ 431; Ex parte Ruddy 121 USPQ 427; In re Wiechert 152 USPQ 249.

For example "Position Isomerism has been used as a tool to obtain new and useful drugs" (Engelhardt), and Position isomerism is a fact of close structural similarity" (Mehta, emphasis in the original).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

April 9, 2003

Bruck Kifle
Primary Examiner
Art Unit 1624